IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 15-1077-SLR
	)	
ALVOGEN PINE BROOK LLC,	)	
	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 16th day of November, 2016, having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent Nos. RE41,408 (" the '408 patent"), RE41,489 ("the '489 patent"), and RE41,571 ("the '571 patent"), shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. "Transdermal delivery system:"[1] "A system that provides delivery of a therapeutically active agent by passage of the active agent from the system through the skin." The specification explains that the purpose of "all sustained-release pharmaceutical preparations" is "to provide a longer period of pharmacologic effect after the administration of a drug than is ordinarily experienced after the administration of immediate release preparations of the same drug." (1:21:25)[2] The specification defines

[1] Found in claims 11, 21, and 23 of the '408 patent; claims 1, 3, 4, 10, 13, 16, and 25-28 of the '489 patent; and claims 1, 22, 24, 43, 45, 48, 50-53, 55, 56, and 60 of the '571 patent.

[2] Citations are to the '571 patent as the specifications are substantially identical.

"sustained release" as "the release of the drug (opioid analgesic) from the transdermal formulation at such a rate that blood (e.g., plasma) concentrations (levels) are maintained within the therapeutic range (above the minimum effective analgesic concentration or "MEAC") but below toxic levels over a period of time of about 3 days or longer." (7:4-10) The claims at issue provide the plasma level or concentration to be achieved. (*See e.g.*, claim 1 of the '571 patent, claim 1 of the '489 patent, and claim11 of the '408 patent) The court cannot discern a need to inject uncertainty into the claims by construing the limitation as proposed by plaintiff – "a system that provides sustained delivery of a therapeutically active agent . . . ."

2. The specification describes a preferred transdermal delivery system, which "include[s] an adhesive layer to affix the dosage form to the skin of the patient for a desired period of administration" (a transdermal patch). (19:14-17; *see also* 1:42-50) Plaintiff's additional proposal of "by adhering to the skin" is not supported by the specification. The claims are directed to human patients and require "contact with the patient's skin," making plaintiff's last addition "from the system through the skin of the patient" unnecessary.

3. **"Mean plasma concentration:"**[3] "The average amount of drug per volume present in the blood-stream at a specified time point." The claims are directed to human patients, making plaintiff's requested addition of "the blood-stream of one or more human patients" unnecessary.

[3] Found in claims 1, 3, 4, 10, 13, 16, and 25-28 of the '489 patent and claims 1, 22, 24, 48, 52, 53, 55, and 56 of the '571 patent.

4. The court has provided a construction in quotes for the claim limitations at issue. The parties are expected to present the claim construction consistently with any explanation or clarification herein provided by the court, even if such language is not included within the quotes.

United States District Judge